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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/913,322	01/15/2002	Wencai Ye	1624-0132P	7072

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EXAMINER	
KRISHNAN, GANAPATHY	

ART UNIT	PAPER NUMBER
1623	9

DATE MAILED: 06/30/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/913,322	YE ET AL.	
	Examiner	Art Unit	
	Ganapathy Krishnan	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-14* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *1-9 and 11* is/are allowed.

6)☒ Claim(s) *10 and 12-14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Amendment B filed September April 14, 2003 has been received, and carefully considered. The following information provided in the amendment affects the instant application:

1. Claims 1-14 have been amended.

2. A substitute specification has been provided.

3. Remarks drawn to the rejections under 35 USC 101 and 112 second paragraph.

Claims 1-14 are pending.

Specification

35 U.S.C. 112, first paragraph, requires the specification to be written in "full, clear, concise, and exact terms." The specification is replete with terms which are not clear, concise and exact. The specification should be revised carefully in order to comply with 35 U.S.C. 112, first paragraph. Examples of some unclear, inexact or verbose terms used in the substitute specification, which are still uncorrected, are:

1. Page 8, line 2 : It is not clear what is meant by "According to the invention, Gymnemic acid compound prefers Gymnemic acid compound of formula I".

2. Page 15, Table 2: The left column still recites glutamic acid 1 through 6. The saccharide part in compounds A and B don't appear to be glutamic acid. The table as such is confusing.

These were a few of the corrections that were pointed out in the previous action. Applicants are requested to go through the specification again and correct these and any

such errors that may still be present. The substitute specification provided has not been entered into record.

Claim Rejections - 35 USC § 101

The rejection of Claim 12 under USC 101 has been overcome by amendment.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 12 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating diseases and conditions associated with hyperglycemia, hyperlipidemia and platelet aggregation, does not reasonably provide enablement for prevention of the said diseases and conditions. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

A conclusion of lack of enablement means that, based on the evidence regarding each of the factors below, the specification, at the time the application was filed, would not have taught one skilled in the art how to make and/or use the full scope of the claimed invention without undue experimentation.

(A) The breadth of the claims

(B) The state of the prior art

(C) The level of predictability in the art

(D) The amount of direction provided by the inventor

(E) The existence of working examples

(F) The quantity of experimentation needed to make or use the invention based on the content of the disclosure.

The breadth of the claims

Claims 12 is drawn to a method of preventing diseases and conditions associated with hyperglycemia, hyperlipidemia and platelet aggregation comprising administering to a patient in need thereof an effective dose of Gymnemic acid derivative of Claim 1 and a pharmaceutically acceptable carrier. The scope of the claim is seen to include the administration of the said compound to a healthy mammal, and subsequent exposure to conditions that would cause the said diseases or conditions, wherein the said compounds prevent said exposure from manifesting itself in said mammal so exposed.

The state of the prior art

The examiner notes that the art cited by the applicants mentions methods for reducing the uptake of glucose in mammals. However, there is no disclosure of potential preventive activity of compounds seen in the prior art. The prior art appears to be silent with regard to preventive procedures recognized by skilled artisans in the field.

The level of predictability in the art

The examiner acknowledges the probability and predictability that administration of the said compounds would have a reasonable expectation of

success for preventing the said diseases and conditions. There is not seen sufficient data to substantiate the assertion that they may be prevented by the use of the compounds instantly claimed.

The amount of direction provided by the inventor

The instant specification is not seen to provide enough guidance that would allow a skilled artisan to extrapolate from the disclosure and the examples provided to enable the use of the active agents to prevent the said diseases and conditions. The specification also fails to direct the skilled artisan in correlative prior art procedures that might provide the basis for an advance in treating the said diseases and conditions which induces prevention of the said disease.

The existence of working examples

The working examples set forth in the instant specification are drawn to data involving mice. The skilled artisan in this field would not extrapolate the preventive efficacy of the compounds claimed or the use of the same in preventive methods from just this example provided. The disclosure does not show the prevention of the said diseases and conditions. However, it is seen to show the effect of the active agents.

The quantity of experimentation needed to make or use the invention based on the content of the disclosure

Indeed, in view of the information set forth, the instant disclosure is not seen to be sufficient to enable the prevention of the said diseases and conditions with the compounds set forth in the claims. A skilled artisan would not

extrapolate the preventive efficacy from the results disclosed for the examples in mice, set forth in the instant specifications.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Most of the 112-second paragraph rejections advanced in the previous action have been overcome. Some new rejections are contained herein below.

Claim10, 13 and 14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 10 recites derivative of claim 1 which contains Gymnemic acid derivative of formula I and/or II and further recites the term composition and the percentages of several components. It is not clear what is being claimed. It has got to be either a derivative with a chemical name or structural formula or a composition. The claim is indefinite. The same recitation is also seen in Claim 14.

Claim 13 b and c still recites the term ointment. It is not clear what the term ointment means and is confusing in the context in which it is used in the claim. The term is generally used to mean a semi solid preparation applied as an external medicament. The term residue is suggested instead of the term ointment. Clarification or amendment is needed as suggested.

However claims 1-14 drawn to Gymnemic acid derivatives, its pharmaceutical compositions, method of extraction and method of treatment of diseases and conditions associated with hyperglycemia, hyperlipidemia and platelets aggregation, seem to be free of prior art.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ganapathy Krishnan whose telephone number is 703-305-4837. The examiner can normally be reached on 8.30am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 703-308-4624. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

JAMES O. WILSON
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600